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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,567	09/05/2006	Joern Borgert	DE 040071	7279

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PHILIPS INTELLECTUAL PROPERTY & STANDARDS
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EXAMINER	
GUPTA, VANI	
ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
06/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,567	BORGERT ET AL.	
	Examiner	Art Unit	
	VANI GUPTA	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. ***Claims 1, 2, and 5 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usami et al. (US 6,610,046 B1) in view of Haim et al. (US 2002/0013615 A1).***

Regarding claims 1 and 2, Usami et al. (hereinafter *Usami*) discloses a catheter apparatus for the therapeutic embolization of aneurysm, the catheter apparatus comprising:

a. a catheter configured to inject a therapeutic drug into a region of interest by means of a pump, where the pump is configured to controllably supply therapeutic drug to the catheter *(col. 3, line 54 – col. 4, line 15; col. 26, ll. 3 - 27).*

However, Usami does not suggest Claim 1 with respect to the features involving the active locator and monitor.

Nonetheless, Haim et al. (hereinafter *Haim*) also suggests a catheter configured to inject a therapeutic drug into a region of interest by means of a pump, where the pump is configured to controllably supply therapeutic drug to the catheter *(paragraphs [0020, [0038, [0109]])*. Hiam et al. also teaches that the method of controlling the supply of a plugging material to a catheter comprising a step of determining the position and/or orientation of the catheter via an active locator fitted thereon (*paragraphs [0111 – 0113]; and **fig. 3***). Details include:

b. an *active locator* comprising a magnetic field sensor, configured to provide coordinates to determine spatial position and orientation of the catheter *(paragraphs [0021], [0023], [0104])*. A locating device *(steering mechanism)* is assigned to the catheter that works in connection with he active locator, and is capable of determining the position and orientation of the catheter (*paragraph [0021]*). In fact, as is known in the art, as the steering mechanism steers the catheter, determining the spatial position and orientation of the catheter would be inherent to the steering process.; and

c. a monitor connected to the active locator and the pump, wherein the monitor is configured to monitor the spatial position and/or orientation of the catheter to detect emergence of the catheter from a region of interest (ROI) during the injection of the drug into the ROI, and configured to stop the supply of the drug in response to the detected emergence *(para. [0028], [0104])*. Haim also explains the importance of proper contact between the catheter and region of interest *(para. [0023])*; and dispensing an appropriate

amount of drug or dispense drug to an "appropriate depth" *(para. [0018])*. Means for ensuring proper contact is also provided *(para. [0071])*.

Accordingly, Usami in view of Haim teaches monitoring the position and orientation of the catheter in the aneurysm; and stopping the administration of the drug if the catheter emerges from the aneurysm.

It would have been prima facie obvious to modify Usami with Haim to include a step of stopping the supply of the plugging material to a catheter if emergence of the catheter from the aneurysm is detected to avoid "deleterious effects" such as "possible systemic toxicity" (*paragraph [0112]*).

Regarding claims 5 and 6, Usami in view of Haim et al. discloses a catheter, a pump device and an electromagnetic locating device, and monitoring capabilities for detecting emergence of the catheter from the region of interest during injection of the drug into the region of interest, and thereupon stopping the supply of the drug *(please see rejections of claims 1 and 2)*.

Additionally, there is control circuitry containing storage space for storing a "road map;" and is designed to record measured position of the locator using the road map. Applicant should note that control circuitry comprises a computer, which would inherently comprise a storage device capable of storing any type of information, including medical image data (*paragraphs [0054 – 0075] and [0108 – 0111]*).

Regarding Claim 7, Haim et al. discloses, via incorporation of ***US 5,568,809*** (paragraph [0105]), that the apparatus of Claim 5 further comprises an imaging device, such as X-ray *(see US 5,568,809: col. 3, lines 43 – 60 and col. 5, lines 31 – 38)*.

Regarding Claim 8, please see rejection of claims 5 and 6; method for performing intended feature is accomplished by electromagnetic active locator.

Regarding Claim 9, Applicant should note that it would be inherent matter of design choice that if Haim et al. discloses a locating device that works in conjunction with a magnetic field sensor device, then the locating device would comprise capabilities for generating an electromagnetic field for the magnetic field sensor to sense.

Regarding Claim 10, Usami teaches that the plugging material can comprise a curable polymer material *(col. 26, line 8)*.

Regarding Claim 11, please refer to rejections of claims 1 and 5.

Regarding Claim 12, Haim et al. teaches that the position of the locator is recorded using a road map generated prior to the step of positioning of the catheter *(paragraph [0110], see last sentence*).

Regarding Claim 13, Haim et al. teaches, via incorporation of ***US 5,568,809*** *(mentioned in paragraph [0105])*, that the catheter and the aneurysm are imaged together at the start of embolization, preferably by means of X-rays or with administration of a contrast agent *(US 5,568,809: col. 3, line 65 – col. 4, line 24)*.

Regarding Claim 14, Usami in view of Haim et al. teaches that the navigation of the catheter in the vascular system is assisted by determining the position of the active locator, as discussed in the rejection of Claim 11.

Response to Arguments

1. ***Applicant's arguments filed March 5, 2010 have been fully considered and are not persuasive.***

Applicant argues that Haim et al., by teaching automatically disabling drug administration in reliance on a contact sensor and the needle retraction mechanism sensor, teaches away from using its positioning sensor to control "injection of the filling material" as recited in claim 1.

Examiner respectfully disagrees and points out that the contact sensor and a positioning sensor, as described by Applicant, are mutually exclusive of each other since Haim suggests or teaches using both *(paragraphs [0104 – 0105])*. Furthermore, Examiner points out that Applicant is arguing semantics, since the contact sensor in and of itself is also a "positioning" sensor, since the contact sensor ensures that the catheter tip is properly placed – or *positioned* – next to the region of interest to "control 'injection of the filling material'" as recited in Claim 1. Please rejection of Claim 1 and paragraphs [0104 – 0105] for more details.

Applicant also argues that Usami in view of Haim does not disclose, suggest, or teach a "catheter apparatus that comprises a monitoring unit comprising 'an active locator configured to provide coordinates to determine a spatial position and/or orientation of the catheter."

In response to applicant's argument that the references fail to show "a monitoring unit comprising 'an active locator'," Examiner respectfully points out that these features upon which applicant relies are not recited in claims 1, 5 and 11. Applicant should note that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Present Claim 1 indicates that the monitoring device is "connected" to an active locator. Usami in view of Haim suggests this as explained in rejection of claim 1. Please see rejection above for further details.

Present claims 5 and 11 indicate, "a monitor *connected* to an active locator (or locating device) and a pump device, the monitor operative to monitor the spatial position and/or orientation of the catheter to detect emergence of the catheter from a region of interest (ROI) during the injection of the drug into the aneurysm, and thereupon stopping the supply of the filling material. Usami in view of Haim suggests as much. Please see rejection of Claim 1 for further details.

Haim also explains the importance of a contact sensor and maintaining proper contact between the catheter and ROI, and its relationship to dispensing an appropriate amount of drug or dispense drug to an "appropriate depth" of the ROI.

Please see also see paragraphs [0018], [0023], [0028], [0071], [0104 – 0105] for further details with respect to rejections of the features discussed in this response section.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANI GUPTA whose telephone number is (571)270-5042. The examiner can normally be reached on Monday - Thursday (8:30 am - 6:00 pm; EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. G./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768